Abd-Elrahman Hamdy Saad Faleh

Driving License: Valid
Marital Status: Married
Nationality: Egyptian
Military status: Exempted
Date of Birth: 3.Dec.1989
Phone Number : 02-35822130
Adress: Elgiza-Elharam
Email: Ar.Alsaady@Gmail.Com
Linkidin: abdelrahman-hamdy-77b608b2
Mobile: (002) 01010012055 - (002) 01110513138

❖ Job Objective

- **Seeking for a challenging position in a well established company through which my skills and Experience will be utilized and where I would be a definite asset .**

❖ Experience

- **Work In Everlife For Pharmaceutical Industries In Drug Regulatory Affairs As Regulatory Affairs Manager and Business Development Manager .** (July 2022 – Up to date)
- **Work In Otsuka Pharmaceutical Company In Drug Regulatory Affairs As Regulatory Affairs Section Head and Business Development Executive .** (Oct 2021 – Jun 2022)
- **Work in International Drug Agency For Pharmaceutical Industries In Drug Regulatory Affairs As Regulatory Affairs Section Head .** (Jan 2021 – Sep 2021)
- **work In Multi-Apex For Pharmaceutical Industries In Drug regulatory affairs as Regulatory Affairs Senior Specialist For 7 Years - Current Employment .** (Dec 2013 – Dec 2020)
- **Work at (CADC) Central Administration For Drug Control at Microbiology Laboratory as Quality Control Specialist .** (Jul 2013 – Nov 2013)
- **Work at (CADC) Central Administration For Drug Control at Pharmaceutics Laboratory as Quality Control Specialist .** (Jan 2013 – Jun 2013)
- **Work at (CADC) Central Administration For Drug Control at Registration Department as Registration Specialist .** (Jun 2012 – Dec 2012)
- **Work at Dr.Abdelrahman Pharmacy as Community Pharmacist .** (Jul 2010 – Up to date)

❖ Duties

➢ Registration responsibilities

- **Manage the whole Regulatory lifecycle activities of the following product types (General,Oncology & Immunosuppressant pharmaceutical products - Herbal,Cosmetic,Biological, Nutritional products – Medical devices) .**
- **Preparing, submitting and following up Registration documents of under-registered, registered & reregistered products to the EDA and related parties to ensure the availability & maintenance of the product in the market .**
- **Continuous Knowledge of new / updated EDA / NFSA decrees,decisions & guidelines and ensures that the company strictly follow all Authority regulations.**

- **Strategic plans for price increase requests .**
- **Archiving all documents, licenses and letters .**
- **Follow up Product Analysis In CADC , NFSA , NORCB .**
- **Licensing new factories and toll companies and stores .**
- **Follow up With EDA Inspection Department Regulatory Issue .**
- **Prepares and submit files and reports to related regulatory authority .**
- **Exportation certificates (CPP, Free sale,GMP) and permission to Export .**
- **Submission for logistics approvals at MOH and custom release for API Excipients .**
- **Coordinate & collaborate with the R&D, Q.C, Production, Marketing team members .**
- **Review of S - Part of raw materials & P-Part for Finished products submitted for MOH .**
- **Follows up batches and raw material submitted samples for analysis till receiving conformity.**
- **Establish and maintain professional relationships with the internal and external stakeholders .**
- **Preparation and submission of all regulatory files (Hard file,pricing,stability file revising,...etc) .**
- **Implementing regulatory activities and ensures compliance with applicable guidelines and SOP.**
- **Track the application deadline updates & gather the required documentation from related parties.**
- **Variation files preparation including (Composition change, Site transfer, Ownership transfer , Supplier addition , Description change, Pack add, …etc) .**
- **Implement and maintain registration tracking system for publishing document submissions either in hardcopy or electronic formats.**
- **Gathering & collecting required information and necessary data to demonstrate the quality, safety and efficacy of products needed in the preparation of Common Technical Dossier .**
- **Follow up the company profile with MOH to assure that our data is correct and if any authority wants to assure the data sent from the company for Exportation.**
- **Interact effectively with all levels of the organization; develop strong working relationships with key stakeholders .**
- **Resolve or follow up complaints to ensure effective and timely resolution of all complaint investigations.**
- **performing the annual importation plans (for Bulk & finished imported products), annual production plans (for raw materials of the locally produced products) & all Importation approvals.**
- **Arranging and dealing with the Supply planner regarding all new and updated products while adhering to regulatory Lead-time.**
- **Responsible for site registration and all audits from foreign health authorities until receiving site registration approval.**
- **Follow up the official websites of the drug authorities to be updates with the new entities, warning and ect.**
- **Follow up the company profile with MOH to assure that our data is correct and if any authority wants to assure the data sent from the company for Exportation.**

➢ **Quality Control responsibilities**

- **Ensure the implementation of GMP program by workers.**
- **Calibrate measurement equipment in the lab according to the approved plan for calibration .**
- **Follow-up cleaning and sanitizing of production line and conduct a report according to the plan.**
- **Inspect and control finished products and ensure its conformity with standards and regulations .**
- **Take retain samples from finished product and store it in main lab store to be as retained sample in case of any complaint.**
- **Provide a full report for what happened in shift on the quality of packed finished product and remarks.**
- **Assist in maintaining the suitable processing programs for processing each class of various product categories to achieve the best results.**
- **Take the necessary procedures in case of any deviation in finished product according to specification and immediately inform production supervisor.**
- **Ensure incoming raw materials quality and their shelf life for processing according to approved specifications.**

❖ Education (2006 – 2011)

- **GPA: 3.1**
- **Grade: Very Good**
- **College: Faculty Of Pharmacy**
- **University: MUST (Misr University For Science And Technology)**

❖ Technical Skills

- **Photoshop: Good**
- **Web Design: Good**
- **Microsoft Office: Very Good**
- **P.C Maintenance: Very Good**
- **Networks Management : Very Good**

❖ Language Skills

- **Native Arabic language.**
- **Very good command of both written and spoken English language.**

❖ Soft Skills

- **Self Motivated,dedicated.**
- **High Communications Skills, Productive relationships.**
- **Planning and Prioritizing tasks according to work needs.**
- **Have good communication , negotiation skills , Problem solving.**
- **Interactive and fast enough to learn new technologies and sciences.**
- **Ability to meet deadlines successfully maintaining the quality of work.**
- **Able to work in group, under pressure, manage stress, teaching others, helpful, creative .**

❖ Training Courses

- **ICDL in MUST university under supervision of UNISCO .**
- **Stress management and community pharmacy by farabi .**
- **CTD& e-CTD dossier building course, with Dr.Magdi Shamaa .**
- **Nanobiotechnology ,stem cells and gene therapy by Biofans team .**
- **Emergency first aid by ICC for the management of medical educatin .**
- **Pharmacovigilance Course organized by Central Administration Of Pharmaceutical Affairs.**
- **Presentation , power of listening , sellin and marketing skills authorized by farabi and multipharma .**
- **Marketing , communication skills , pharmaceutical advertising & promotion and leader ship by EPSF.**
- **Attending CTD & e-CTD Course presented by Dr. Hasan Mustafa (Vice Chairman of REYADA PRO) at the Scientific Office for System and Solution Design.**

❖ Summer Training

- **Summer 2011 : Medical rip at Proact Sigma .**
- **July - Sep (2007,2008,2009,2010) : Community Pharmacist At DR. Samy Pharmacy .**

Thank you for spending time reading my CV. & all my hopes are to join your team

References will be furnished upon request